

REMARKS

This responds to the Office Action dated July 24, 2006 (hereinafter “Office Action”), and the references cited therewith. Claims 1-2, 8, 11-12, 23, 29, and 33-34 are amended and fully supported by the application as filed. Claims 15-20 were previously canceled without prejudice or disclaimer. Claims 4, 8-14, and 27-36 have been previously withdrawn, but should be considered upon the allowance of generic claim 1. Claims 37-42 are added and fully supported by the application as filed. Accordingly, claims 1-14 and 21-42 are now pending in this patent application.

§102 Rejection of the Claims

1. Claims 1-3, 5, 6-7, and 23-25 were rejected under 35 U.S.C. § 102(b) as being anticipated by Cross, Jr. et al., (U.S. Patent No. 5,935,159). Applicant respectfully traverses on the ground that Cross, Jr. et al. does not disclose all elements of such claims.

Claim 1:

Applicant cannot find each element of claim 1 in Cross, Jr. et al. According to the Federal Circuit, “[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983). Claim 1 recites an implantable lead comprising “one or more fillers disposed within the tubular lead body, the one or more fillers are disposed adjacent to the insulated at least one conductor and include one or more recesses; and the at least one conductor is disposed outside the one or more recesses.” In contrast to claim 1, Cross, Jr. et al. recites:

An improved lead body for implantable leads comprising a longitudinally extending core section provided with longitudinally extending grooves in which conductors are located and an outer tubular member, encasing the core and conductors.

(Cross, Jr. et al. at Abstract; *see also* col. 1, lines 21-24 and 28-29).

Because each element of Applicant’s claim 1 cannot be found in Cross, Jr. et al., Applicant respectfully requests withdrawal of this basis of rejection of claim 1. Claims 2-3, 5-7,

21, and 23-26 are dependent on claim 1 and are patentable for the reasons stated above, in addition to the elements recited in such claims.

Claims 2-3:

Additionally, regarding claims 2-3, Applicant cannot find any recitation in Cross, Jr. et al. of one or more fillers including one or more recesses wherein “the one or more recesses include compression features,” as recited in claim 2, or wherein “the compression features include compression waves,” as recited in claim 3. The Office Action asserts that the “radially extending portions (180, 182, 184, 186)” comprise the compression features and the longitudinally extending grooves “(190, 192, 194, 196)” comprise the compression waves. (Office Action at page 3). However, as stated above, Cross, Jr. et al. expressly recites:

[L]ongitudinally extending grooves in which conductors are located and an outer tubular member, encasing the core and conductors . . . [t]ube 100 has an inner diameter approximately equal to the outer diameter of core 102.

(Cross, Jr. et al. at Abstract; col. 3, lines 25-26). Applicant submits the disposition of the conductors into the grooves of Cross, Jr. et al. in conjunction with approximately equal inner tube diameter and outer core diameter does not allow for the presence of compressive recesses (e.g., compression waves) as claimed.

Because each element of Applicant’s claims 2-3 cannot be found in Cross, Jr. et al., Applicant respectfully requests withdrawal of this basis of rejection of claims 2-3.

Claim 6:

Additionally, regarding claim 6, Applicant cannot find any recitation in Cross, Jr. et al. of one or more fillers “generally C-shaped,” as recited in claim 6. The Office Action asserts FIG. 2 of Cross, Jr. et al. discloses the claimed shape; however, Cross, Jr. et al. expressly recites:

Core 102 is provided with four radially extending portions 180, 182, 184 and 186 which extend longitudinally along the length of the core.

(Cross, Jr. et al. at col. 2, lines 35-36). Applicant submits the four radially extending core portions of Cross, Jr. et al. results in a core that is generally X-shaped.

Because each element of Applicant’s claim 6 cannot be found in Cross, Jr. et al., Applicant respectfully requests withdrawal of this basis of rejection of claim 6.

Claim 23:

Additionally, regarding claim 23, Applicant cannot find any recitation in Cross, Jr. et al. of one or more fillers “longitudinally extending from a first end to a second end, and at least a first and a second insulated cable conductor are disposed distally between the first and second ends,” as recited in claim 23. The Office Action asserts the core illustrated in FIG. 2 of Cross, Jr. et al. discloses “one or more fillers includ[ing] a first end and a second end”, and FIG. 3 illustrates “at least a first and a second insulated cable conductor are disposed between [the] first and second ends.” (Office Action at page 3). Applicant submits this asserted core does not longitudinally extend from a first end to a second end, and further the conductors are not disposed distally between the first and second ends, both of which are elements claimed by Applicant.

Because each element of Applicant’s claim 23 cannot be found in Cross, Jr. et al., Applicant respectfully requests withdrawal of this basis of rejection of claim 23.

Claim 24:

Additionally, regarding claim 24, Applicant cannot find any recitation in Cross, Jr. et al. of an implantable lead comprising “an active fixation assembly disposed at a distal end of the tubular lead body,” as recited in claim 24. The Office Action asserts “an insulative tine sheath 14” of Cross, Jr. et al. comprises the claimed active fixation assembly. (Office Action at page 3; Cross et. al. at col. 2, line 4). Applicant submits the tine sheath comprises a passive fixation assembly in contrast to the active fixation assembly claimed. An active fixation assembly may, for example, extend or retract from the lead body unlike a passive fixation assembly.

Because each element of Applicant’s claim 24 cannot be found in Cross, Jr. et al., Applicant respectfully requests withdrawal of this basis of rejection of claim 24.

§103 Rejection of the Claims

1. Claim 21 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Cross, Jr. et al., (U.S. Patent No. 5,935,195) as applied to claim 1 above, and further in view of Kuzma, (U.S. Publication No. 2003/0236562). Applicant respectfully traverses such rejection on the

grounds that the combination of Cross, Jr. et al. and Kuzma (1) fails to establish all elements of such claim and (2) is improper.

Applicant cannot find all elements of claim 21 in Cross, Jr. et al. nor Kuzma, alone or in combination. According to the M.P.E.P. § 2142, the prior art reference(s) must teach or suggest all of the claim elements. Claim 21 recites an implantable lead wherein “a flexibility of the one or more fillers is greater than a flexibility of the tubular lead body.” The Office Action expressly admits that Cross, Jr. et al. fails to recite such elements, but asserts Kuzma recites the missing subject matter at paragraph [0055], lines 14-15. (Office Action at page 4). However, Applicant points out that at such cited portions, Kuzma recites:

A suitable filler material, for example, is a type of silicone polymer or silicone rubber known as LSR-70.

Applicant further points out that Cross, Jr. et al. recites:

[I]n the context of implantable pacing and defibrillation leads, an inner core 102 fabricated of a polyurethane and outer tube of silicone rubber, is to be particularly desirable.

(Cross, Jr. et al. at col. 3, lines 11-13). That is to say, the combination of Kuzma and Cross, Jr. et al. recites the use of the same material for fabrication of the core and the outer tube; however, Applicant's claim 21 requires the filler material to have a flexibility greater than a flexibility of the tubular lead body.

In addition to not establishing all elements of claim 21, Applicant asserts the combination of Cross, Jr. et al. and Kuzma does fail to possess legally sufficient motivation. According to the Federal Circuit in *In re Lee*, “there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant.” 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002). However, such motivation to combine is lacking when the references involve mere trade-offs. See *Winner International Royalty Corp. v. Wang*, 202 F.3d 1340, 53 U.S.P.Q.2d 15080 (Fed. Cir.), cert. denied, 530 U.S. 1238 (2000)(stating motivation to combine requires desirability, not merely a trade-off). As discussed above, Kuzma recites the use of silicone polymer or silicone rubber filler material and Cross, Jr. et al. recites the use of a polyurethane inner core and a silicone rubber outer tube. Cross, Jr. et al. further recites “[t]he core and tube may also be fabricated of the same material.” (Cross, Jr. et al. at col. 3, lines 13-14). Since Cross, Jr. et al., alone, recites that the core and tube may comprise the same material,

there is no motivation to combine such reference with Kuzma which also recites using a core silicone filler material resulting in a core and tube of the same material.

Thus, because (1) Cross, Jr. et al. and/or Kuzma fail to establish all elements of claim 21 and (2) there is no legally sufficient motivation to combine such references as they involve mere trade-offs, Applicant respectfully requests withdrawal of this basis of rejection of claim 21.

2. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr. et al., (U.S. Patent No. 5,935,195) as applied to claim 1 above, and further in view of Bush, (U.S. Patent No. 5,755,762). Applicant respectfully traverses on the grounds that (1) no specific reason supporting the combination of Cross, Jr. et al. and Bush has been provided and (2) Cross, Jr. et al. arguably teaches away from such combination.

Applicant submits that no specific reason supporting the combination of Cross, Jr. et al. and Bush has been provided. According to the Board in *Ex parte Humphreys*, if the Examiner does not provide a specific reason to support an obviousness rejection, he or she will have failed to establish a *prima facie* case of obviousness, and the Applicant's application will be allowed over the prior art. 24 U.S.P.Q.2d 1255 (B.P.A.I. 1992). The Office Action expressly admits that Cross, Jr. et al. fails to recite the elements of claim 26 (including "an outer surface portion of the at least one cable conductor contacting an outer surface portion of the coiled conductor"); however, asserts that Bush recites the missing subject matter and it would have been obvious to combine such references "to optimize lead performance." (Office Action at page 4). To the extent that this statement is based on the Examiner's personal knowledge, Applicant respectfully objects to any such reliance on Official Notice, and respectfully requests that the Examiner either cite at least one reference in support of this position, or alternatively, provide an affidavit to provide objective evidence of record of the same, pursuant to M.P.E.P. § 2144.03. Further, Applicant submits that such obviousness assertion is vague and fails to meet the requirements set forth by the Board in *Ex parte Humphreys*. Notably, the same vague obviousness assertion was used to support the combination of Cross, Jr. et al. and Kuzma.

In addition to lacking a specific reason to combine, Cross, Jr. et al. arguably teaches against being combined with Bush. According to the Federal Circuit, motivation to combine is lacking when the references teach away from the claimed combination. See *Bausch & Lomb*,

Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 230 U.S.P.Q. 416 (Fed. Cir. 1986)(stating, a reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered). The Office Action asserts that Bush recites “an outer surface portion of at least one cable conductor contacting an outer surface portion of a coil conductor.” (Office Action at page 4). In contrast to such side-by-side placement of the coil and cable conductors, Cross, Jr. et al. recites the placement of conductors in grooves, such grooves being separated by radially extending core portions. (See Cross, Jr. et al. at col. 2, lines 33-51).

Thus, because (1) no specific reason supporting the combination of Cross, Jr. et al. and Bush has been provided and (2) Cross, Jr. et al. arguably teaches against such combination, Applicant respectfully requests withdrawal of this basis of rejection of claim 26.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 24 day of October 2006.

Name

Signature